

REMARKS

The Office Action mailed August 12, 2004, has been received and reviewed. Claims 1 through 20 were noted as pending in the Office Action. Claims 3 through 17 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1, 2, and 18 through 20 stand rejected. Applicant has amended claims 1, 2, 18, 19 and 20, and added new claims 21 and 22. Support for the claim amendments may be found at paragraph [0010] and in Example 9 of the as-filed application. Reconsideration of the application as amended herein is respectfully requested.

35 U.S.C. § 112 Rejections

Rejections under 35 U.S.C. § 112, ¶ 2

Claims 1, 2 and 18 through 20 were rejected in the Office Action as assertedly being indefinite under 35 U.S.C. § 112, second paragraph. The Office Action states that the phrase “biologically active” renders each of the claims vague and indefinite as “the phrase is not always interpreted as limiting the polypeptide to being enzymatically active, but also includes other biological functions such as being able to generate antibodies to the polypeptide.” (Office Action at page 2). Accordingly, applicant has amended these claims to remove this phrase. Independent claim 1 now recites “phosphorylated polypeptide having protein methylglyoxal modifying activity,” which language is directed to a specific activity. Support for this amendment may be found at paragraph [0010] and Example 9 of the as-filed application. Accordingly, it is requested this rejection be withdrawn.

The Office Action further asserts that the phrase “treating a cell” renders claim 18 indefinite as “it is not certain what specific types of cells are encompassed by the phrase.” (*Ibid.*) Amended claim 18 now recites “treating a mammalian cell,” support for which can be found in the Examples of the as-filed specification. Applicant thus requests this rejection be withdrawn.

Rejections under 35 U.S.C. § 112, ¶ 1

Claim 18 was rejected in the Office Action as assertedly lacking enablement under 35 U.S.C. § 112, first paragraph. The Office Action states that the specification “while being

enabling for treating a mammalian cell with TNF in the production of the glyoxalase I of claim 1, does not reasonably provide enablement for treating any cell such as a bacterial cell or fungal cell in the production of the glyoxalase I of claim 1.” (Office Action at page 3). As discussed previously herein, amended claim 18 now recites “treating a mammalian cell.” Accordingly, it is requested this rejection be withdrawn and the claim allowed.

Claims 1 and 18 were rejected in the Office Action as assertedly failing to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. The Office Action states that applicant’s position is that the claims recite “a human phosphorylated glyoxalase I and that the specification provides an adequate written description for a human phosphorylated glyoxalase I,” but that the “Examiner respectfully disagrees” for a number of reasons. (Office Action at page 4).

Amended claim 1 is directed to an “isolated phosphorylated polypeptide having protein methylglyoxal modifying activity.” Support for this amendment may be found at paragraph [0010] and Example 9 of the as-filed specification. Previously, methylglyoxal modification of protein was considered a non-enzymatic process (*see e.g.*, Oya et al., J. Biol Chem 274, 18492-18502, 1999) and a specific enzyme capable of protein glycation had not been demonstrated.

The demonstration of an enzyme capable of enzymatic glycation of proteins supports the allowability of the scope of the present claims. As noted in the Office Action, in order to support such a genus claim, “at least one species of the claimed genus” must be described and “common characteristics of the claimed molecules” must be identified. As applicant has provided both a description of at least one species of an enzyme capable of protein glycation and identified at least one common characteristic thereof (the protein methylglyoxal modifying activity), it is requested this rejection be withdrawn and amended claims 1, 2, and 18 be allowed.

35 U.S.C. § 103(a) Obviousness Rejections

Claims 1, 2, and 18 stand rejected in the Office Action under 35 U.S.C. § 103(a) as assertedly being obvious over Ranganathan et al. (J Biol Chem 1993 Mar 15; 268(8):5661-7) in view of Pestka et al. (Protein Expr Purif 1999 Nov; 17(2):203-14). Applicant submits that the amended claims define over the combination of references suggested in the Office Action.

In order to establish a case of obviousness, a prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (MPEP 706.02(j), citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). As amended, claim 1 is directed to an "isolated phosphorylated polypeptide having protein methylglyoxal modifying activity." Neither Ranganathan et al. or Pestka et al. teaches or suggests an isolated phosphorylated polypeptide having protein methylglyoxal modifying activity.

In the prior Amendment, applicant submitted that there was no motivation to combine these references as suggested in the Office Action, since the cited references support a conclusion that one of ordinary skill in the art would not be led to expect that phosphorylation of glyoxalase would lead to the biologically active form. As previously noted herein, amended claim 1 is directed to an "isolated phosphorylated polypeptide having protein methylglyoxal modifying activity." Previously, methylglyoxal modification of protein was considered a non-enzymatic process (*see e.g.*, Oya et al., J. Biol Chem 274, 18492-18502, 1999) and a specific enzyme capable of protein glycation had not been demonstrated. Thus, one of ordinary skill in the art would not be able to predict the methylglyoxal modifying activity of such a polypeptide and the phosphorylation thereof, supporting a conclusion that a motivation to combine these references is lacking. Accordingly, it is requested this rejection be withdrawn and the claims allowed.

New Claims

New claim 21 is based on the language suggested by the Examiner in the Office Action at page 2, numbered section 3.

As discussed previously herein, the Office Action (at page 3) states that the specification is "enabling for treating a mammalian cell with TNF in the production of the glyoxalase I of claim 1." New claim 22 is directed to this subject matter noted as enabled in the Office Action.




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CONCLUSION

All pending claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact applicant's undersigned attorney.

Respectfully submitted,


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